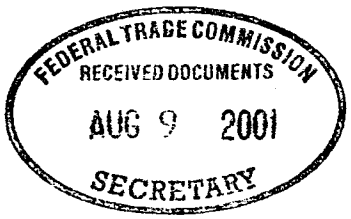
UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION



In the Matter of	)	
Schering-Plough Corporation, a corporation,	)	Docket No. 9297
Upsher-Smith Laboratories, a corporation,	)	
and	)	
American Home Products Corporation, a corporation.	)	

TO: The Honorable D. Michael Chappell
Administrative Law Judge

ANDRX PHARMACEUTICAL, INC.'S AND AVENTIS PHARMACEUTICAL INC.'S JOINT MOTION FOR A PROTECTIVE ORDER PRECLUDING THE PRODUCTION OF DOCUMENTS AND MATERIALS PRODUCED IN *IN THE MATTER OF HOECHST MARION ROUSSEL, INC.*, DOCKET NO. 9293 TO RESPONDENT AMERICAN HOME PRODUCTS CORPORATION

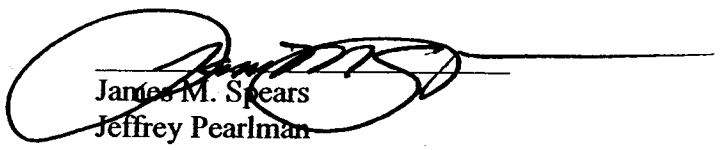
Pursuant to Rule 3.31 of the Federal Trade Commission's Rules of Practice, non-parties Andrx Pharmaceuticals, Inc. and Aventis Pharmaceuticals Inc. hereby move for a protective order precluding Complaint Counsel from producing to respondent American Home Products documents and materials produced by Movants in *In the Matter of Hoechst Marion Roussel, Inc.*, Docket Number 9293.

Respondent American Home Products Corporation in this action has filed a Motion to Compel Counsel to Search the Federal Trade Commission for Responsive Documents. Because the documents sought in this motion would partially derive from the production of Movants' documents in a previous litigation, Movants seek relief from this tribunal. As demonstrated in

the accompanying Memorandum submitted herewith, protective action should be taken because (1) the documents sought are irrelevant to the current proceeding; (2) substantial prejudice to Movants would follow if Respondent's motion was not limited to exclude Movants' documents; and (3) Respondent has failed to show an adequate need for these documents given the alternative routes of discovery available. The bases of this motion are set forth in the accompanying Memorandum in Support of Motion for Protective Order and Declarations of James M. Spears and Colin A. Underwood unless otherwise noted.

Dated: August 9, 2001

Respectfully submitted,



James M. Spears
Jeffrey Pearlman
Ropes & Gray
1301 K Street, N.W.
Suite 800 East
Washington, DC 20005
(202) 626-3981
Attorneys for Aventis Pharmaceuticals, Inc.

Colin Underwood by

Louis M. Solomon
Colin A. Underwood
Solomon, Zauderer, Ellenhorn, Frischer & Sharp
45 Rockefeller Plaza
7th Floor
New York, New York 10111
(212) 956-3700
Attorneys for Andrx Pharmaceuticals, Inc.

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

In the Matter of	)	
Schering-Plough Corporation, a corporation,	)	Docket No. 9297
Upsher-Smith Laboratories, a corporation,	)	
and	)	
American Home Products Corporation, a corporation.	)	

ORDER GRANTING ANDRX PHARMACEUTICAL, INC.'S AND AVENTIS PHARMACEUTICAL INC.'S JOINT MOTION FOR A PROTECTIVE ORDER PRECLUDING THE PRODUCTION OF DOCUMENTS AND MATERIALS PRODUCED IN *IN THE MATTER OF HOECHST MARION ROUSSEL, INC.*, DOCKET NO. 9293 TO RESPONDENT AMERICAN HOME PRODUCTS CORPORATION

IT IS HEREBY ORDERED that Andrx Pharmaceuticals, Inc.'s and Aventis' Pharmaceuticals Inc.'s motion is GRANTED; under the Protective Order, documents and materials requested by American Home Products Corporation and produced by Movants in *In the Matter of Hoechst Marion Roussel, Inc.*, Docket No. 9293 will not be subject to American Home Products Corporation's document request.

D. Michael Chappell
Administrative Law Judge

Date: _____, 2001

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

In the Matter of	)	
Schering-Plough Corporation, a corporation,	)	Docket No. 9297
Upsher-Smith Laboratories, a corporation,	)	
and	)	
American Home Products Corporation, a corporation.	)	

TO: The Honorable D. Michael Chappell
Administrative Law Judge

MEMORANDUM IN SUPPORT OF ANDRX PHARMACEUTICAL, INC.'S AND AVENTIS PHARMACEUTICAL INC.'S JOINT MOTION FOR A PROTECTIVE ORDER PRECLUDING THE PRODUCTION OF DOCUMENTS AND MATERIALS PRODUCED IN *IN THE MATTER OF HOECHST MARION ROUSSEL, INC.*, DOCKET NO. 9293 TO RESPONDENT AMERICAN HOME PRODUCTS CORPORATION

I. INTRODUCTION

On June 1, 2001, Respondent American Home Products Corporation ("AHP") filed a document request with Complaint Counsel in the above-referenced matter seeking the production of certain documents from the Federal Trade Commission ("FTC"), including documents and materials which were produced by parties and third parties in *In the Matter of Hoecht Marion Roussel, Inc.* Docket No. 9392.[1] On or about July 25, 2001, non-parties Andrx

[1] The facts relied on in this motion rely upon the accompanying Declarations of James M. Spears and Colin A. Underwood. Andrx and Aventis as non-parties have not been privy to communications between Complaint Counsel and AHP, have not had access to the pertinent documents in the possession of the FTC, and, as described *infra*, have only recently had access to the discovery requests underlying this dispute. AHP has had months to craft its motion; Andrx and Aventis have had about a week-and-a-half to properly respond. As AHP's arguments lack

Pharmaceuticals, Inc. ("Andrx") and Aventis Pharmaceuticals Inc. ("Aventis") received copies of Respondent AHP's July 23, 2001 Motion to Compel Complaint Counsel ("Resp. Mot.") to Search the Federal Trade Commission for Responsive Documents, which also contained a copy of the original documents request, Complaint Counsel's Objections and Responses dated June 25, 2001, as well as the other documents filed by Respondent AHP in support of its motion.

AHP is a party and a Respondent to this action by the FTC. The FTC has issued an administrative complaint against AHP alleging that the company has violated Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45. The FTC alleges that Schering-Plough Corporation ("Schering"), Upsher-Smith Laboratories ("Upsher-Smith"), and AHP have delayed the entry of low-cost generic competition to Schering's prescription drug K-Dur 20, a sustained release formulation of potassium chloride. *See* Complaint ¶ 1. The FTC alleges that Schering entered into agreements with Upsher-Smith, ESI Lederle, Incorporated ("ESI"), a division of AHP, as well as AHP itself, which preclude potential generic entrants Upsher-Smith, ESI, and all other potential generic competitors from entering the market. *See* Complaint ¶ 2. Aventis is not implicated directly or indirectly in the facts of this case in any way. As the filer of an Abbreviated New Drug Application ("ANDA") for a generic form of K-Dur, Andrx has been affected by Respondents' conduct and in fact has already produced material to the FTC during the pre-complaint investigation – material that (Andrx understands) has already been disclosed to Respondents (Declaration of Colin A. Underwood ¶¶ 5, 6). In addition, AHP has served a subpoena duces tecum on Andrx seeking additional material concerning Andrx's ANDA and its plans for its generic K-Dur product (Underwood Decl. ¶ 7 & Ex. A). Neither Andrx nor Aventis

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legal merit, however, Andrx's and Aventis' limited knowledge of the facts of this matter is sufficient for this joint motion.

has entered into an agreement or otherwise engaged in any conduct which might preclude or delay anyone from entering a market for sustained release potassium chloride.

Still, AHP demands discovery documents produced in an unrelated litigation, *In the Matter of Hoecht Marion Roussel, Inc.* Docket No. 9392 ("HMR" or "HMR Litigation") in which Andrx and Aventis were involved.[2] The FTC in that case filed a complaint alleging that Hoechst Marion Roussel, Inc., Carderm Capital L.P., and Andrx engaged in conduct that discouraged the entry of generic versions of Cardizem CD, a once-a-day diltiazem product. Andrx and Aventis produced tens of thousands of pages of documents and other materials in compliance with the FTC's discovery requests during this proceeding. These document productions were deemed solely for use by the parties to that action for the purposes of that action, and not for any other purpose. *See* Protective Order, April 28, 2000, at 5. The allegations in that matter have since been resolved. *See* Agreement Containing Consent Order, Docket No. 9293, FTC (April 4, 2001). Shortly thereafter, Counsel for both Aventis and Andrx requested the return of all documents and materials submitted to the Commission as provided by 15 U.S.C. § 57b-2(b)(5) and 16 C.F.R. § 4.12(a)(2).[3] However, before the custodian of the documents could secure and prepare the documents for their return, Respondent AHP filed the document request that is now the subject of this proceeding. *See* Resp. Mot. at 10.

AHP demands documents produced in the HMR litigation through its First Set of Document Requests, including, but not limited to, the items in its First Set of Document

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[2] As explained *infra*, AHP's decision to seek this Andrx and Aventis material from Complaint Counsel, instead of requesting it directly from the companies themselves, contributes to the substantial prejudice of Andrx and Aventis.

[3] Counsel for Aventis Pharmaceuticals Inc. filed a letter in behalf of Aventis requesting the return of the documents on May 17, 2001. *See* Attachment A to Declaration of James M. Spears.

Requests Nos. 17, 20, 21, 22-27, 30, 37, 41-44, and 46-48. *See* Respondent American Home Products Corporation's First Set of Document Requests. As characterized by AHP, these documents relate to "core issues" in the present matter. *See* Resp. Mot. at 3. AHP argues that paragraphs 17-19 of the Complaint contain "several general allegations" about the "impact of generic competition" on branded pharmaceutical market shares, and that accordingly AHP's First Set of Document Requests Nos. 22-27 "request documents regarding the effect of generic entry on a branded pharmaceutical product's market share." *See id.* These and other issues such as the issue of licensing of generic products "underlie the Commission's theory of harm" and documents "related" to them would be "highly relevant under any test," according to AHP. *See id.*

II. STANDARD OF REVIEW

In order to obtain the documents it now seeks, AHP must demonstrate that the scope of discovery is "reasonably expected to yield information relevant to the allegations of the complaint, to the proposed relief, or to the defense of any respondent." 16 C.F.R. § 3.31(c)(1). That is, the information sought must be "reasonably relevant" to the charges asserted in the complaint, or the defenses to the complaint. *See FTC v. Anderson*, 631 F.2d 741, 745-46 (D.C. Cir. 1979) (stating that both the relevancy of an adjudicative subpoena and an investigative subpoena are governed by reasonable relevance). Where documents, such as those from the HMR Litigation, contain confidential business information or would disclose trade secrets, the standard is more exacting and the party seeking production of the documents must establish that the documents sought are relevant *and* that the party seeking production has a specific need for the documents in order to prepare for trial. *See Pioneer Hi-Bred Int'l, Inc. v. Holden's Found. Seeds, Inc.*, 105 F.R.D. 76, 81-82 (N.D. Ind. 1985).

Even where relevance can be established, the right of the requesting party to obtain documents is weighed against the prejudice that might be caused to third parties in the event that production were ordered. This is particularly true where the document request implicates "the rights of third parties who have complied with investigatory demands and the public interest in minimizing disclosure of confidential documents produced in investigations[.]" *In the Matter of Hoechst Marion Roussel, Inc., Carderm Capital L.P., and Andrx Corp.*, Docket 9293, 2000 FTC LEXIS 134 (Aug. 18, 2000), ("HMR August 18, 2000 Order") at *13-14.

Finally, the right of the requesting party to compel production of the requested documents is also assessed in terms of the burden that the request imposes upon this tribunal, the parties to this action and third parties whose interests may be implicated by the production request. Specifically, the Administrative Law Judge is permitted to limit discovery if the evidence shows that

> (i) The discovery sought is unreasonably cumulative or duplicative, or is obtainable from some other source that is more convenient, less burdensome, or less expensive;
>
> (ii) The party seeking discovery has had ample opportunity by discovery in the action to obtain the information sought; or
>
> (iii) The burden and expense of the proposed discovery outweigh its likely benefit. 16 C.F.R. § 3.31(c)(1)(i-iii).

ARGUMENT

AHP's argument that it is entitled to compel the production of HMR Litigation documents lacks merit. First, AHP has failed to establish that the documents demanded are reasonably relevant to the case at hand or that they are reasonably necessary to respond to the Complaint or to present the basis for Respondent's defense. AHP's argument that it is entitled to have access to tens of thousands of pages of confidential documents on the supposition that

certain statements made by Complaint Counsel in the course of these proceedings might have relied on information contained in such documents is make-weight and fails to meet the threshold requirements of relevancy and need.

The prejudice of forcing non-parties Aventis and Andrx to place tens of thousands of pages of irrelevant but nonetheless confidential documents into the record of this proceeding is also manifest. As non-parties to this proceeding, Aventis and Andrx lack the fundamental ability to protect the confidential nature of these documents and, at best, have only derivative rights through Complaint Counsel to monitor and direct the production demanded. Similarly, the confidentiality concerns of third parties who may have produced confidential documents in the HMR litigation are wholly ignored in this process.

Of course, these concerns regarding prejudice could largely have been obviated had AHP served appropriately specific discovery on Aventis, Andrx and any other third party whose confidential documents might be implicated by AHP's document request. In that manner, the third party whose documents are sought by AHP could appear in its own right to challenge or contest the scope or substance of any document request. Particularly, given AHP's service of a subpoena on Andrx -- after it filed its motion against Complaint Counsel -- which does not seek this material directly from Andrx, AHP's choice to pursue discovery in such an obnoxious and burdensome fashion is indefensible.

1. AHP Has Failed to Establish the Relevance of HMR Litigation Documents to This Litigation

A. AHP cannot establish a direct or indirect link between the documents sought from the HMR Litigation and the matters at issue in the K-Dur 20 Litigation

Any settlement generated out of or produced in the HMR Litigation, when viewed in the context of the allegations brought by the Complaint Counsel in this matter, cannot have

any relevance to the Complaint.[4] The requested documents concern distinct and unrelated products, do not involve products in the K-Dur 20 market, and so cannot have any effect on any potential harms the Schering-ESI-AHP agreement might have had on any potentially relevant market. The requested documents also do not involve any aspect of any transaction that the Respondents entered into with respect to K-Dur 20. AHP cannot establish, therefore, an indirect link between the subject matter of this litigation and the HMR Litigation, let alone a direct one.

The HMR Litigation was born out of concerns over unlike markets, products, patents, and agreements, and so can not benefit this litigation, except to broaden the subject matter to the point of absurdity. *See Metagenics, Inc.*, 1995 FTC Lexis 78 (April 10, 1995), at *2 (denying request for documents obtained in other investigations, stating "The only relevant documents in this case are those which relate to the investigation which led to this proceeding, not those which may have been gathered in other investigations . . . ."); *In the Matter of the Kroger Co.*, 1977 FTC LEXIS 55 (Oct. 27, 1977), at *4 (finding Commission's prior proceedings "clearly irrelevant" to pending dispute). Consequently, nothing in the facts of the HMR Litigation suggests that documents pertaining to that case are relevant here in that that case pertains to different products, markets and parties than are at issue here. Consequently, absent some specific showing of relevance, AHP cannot meet its threshold burden in order to compel the production of these sensitive third-party documents.

[4] The Complaint alleges anticompetitive conduct arising out of settlements among Schering, Upsher-Smith, and AHP to delay the entry of low-cost generic competition to Schering's K-Dur 20. The Complaint alleges, for example, that Schering, ESI, and AHP settled patent infringement litigation because Schering agreed to pay ESI up to $30 million in exchange for AHP and ESI refraining from marketing their generic version of K-Dur 20 for a set period and limiting their activity with respect to a generic version of the drug after that period. *See generally* Complaint.

B. Occasional statements made by Complaint Counsel regarding practices general to the pharmaceutical industry are insufficient to establish relevance or substantial need.

AHP argues that it meets its obligations to establish both relevance and "substantial need" with respect to the documents sought by pointing to generalized comments regarding industry practices made by Complaint Counsel during this proceeding and presuming, without proof or support, that such statements were based on information gleaned from the confidential HMR Litigation documents. Not surprisingly, AHP cites no case—and there is none—that supports the notion that generalized statements like these made by Complaint Counsel in the course of administrative litigation can give rise to the wholesale production of confidential third-party documents.

While AHP argues that these odd statements rely upon "an understanding based on instances that may transcend beyond the investigation of this case", *see* Resp. Mot. at 11, nothing but supposition supports AHP's assertion that Complaint Counsel's statements were based whole or in part upon the confidential documents produced in the HMR Litigation. Indeed, AHP's position is a classic bootstrap that would hold confidential documents relevant and therefore subject to discovery because AHP presumes them to be so.

Closer examination of AHP's specific "claims" reveals the extent to which AHP's claims of relevancy are the product of guesswork and supposition. For example, AHP seizes upon a statement made by Complaint Counsel Karen Bokat, who expressed the view that "Schering didn't perform the normal due diligence on Niacor that a company would perform when licensing a new product." AHP's analysis of this statement assumes that Complaint Counsel must have learned about due diligence in licensing transactions only from other pending and closed investigations. Because the issue of how due diligence is properly performed when a

pharmaceutical company licenses a new product did not arise in the HMR Litigation,[5] it is unlikely that Ms. Bokat would have relied upon the Aventis/Andrx documents in forming her opinion on this subject.

Similarly, AHP relies upon a statement made by Ms. Bokat regarding the flow of royalties from licenses derived from patent litigation as giving AHP a right to sweep though the confidential Aventis/Andrx documents from the HMR Litigation. Again, it is not likely that Ms. Bokat relied upon any evidence from the HMR Litigation when she made this statement because, as this tribunal knows, the HMR/Andrx patent litigation was settled, without any licensing provision whatsoever, when Andrx invented around HMR's patent. No royalties were ever paid in the HMR/Andrx case. Thus it is very unlikely that Ms. Bokat's statement was derived from information produced in the HMR Litigation.

The final statement seized upon by AHP to justify discovery here is the statement in the Complaint that:

> "[g]eneric entry generally leads to a significant erosion of the branded drug's market share and unit and dollar shares within the first year. As additional generic drugs enter, the price of the generic drugs typically decreases even further and the branded drug's market share erodes further."

Resp. Mot. at 11 (emphasis in Resp. Mot. omitted). AHP argues that Complaint Counsel could not have formed an opinion about what "generally" or "typically" occurs to the market share of the branded product or the price of generics when generic entry occurs without drawing from information gleaned from the Commission's other non-public investigations. Resp. Mot. at 12.

Aventis and Andrx would respectfully submit that it is hardly surprising that the market share of a branded pharmaceutical tends to decrease upon generic entry or that the price

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[5] Complaint Counsel, in fact, emphatically denies that it is relying on information from other investigations to prosecute its Complaint. *See* Complaint Counsel's Opposition to

of the first generic might fall when the second or third generic enters the market. Regardless of where the Commission came across this relatively self-evident economic fact, it cannot be that the application of elementary economic theory by Commission in its Complaint is sufficient to give a Respondent the right to peruse tens of thousands of pages of confidential third-party documents in the off chance that something relevant might be discovered.

Indeed, under the rudderless and limitless standard offered by AHP here, the totality of human knowledge on any single sentence in the Complaint would be subject to AHP's discovery requests. Allowing AHP to proceed *carte blanche* would allow the discovery seeker access to whatever it wanted so long as it could point to any statement of opposing counsel and hypothetically suppose that statement was drawn from some body of confidential information.

At bottom, AHP has not shown how the documents subject to its request are relevant to this matter, much less that it has established that a substantial need exists for AHP to obtain access to the HMR documents. Accordingly, even without reference to the prejudice element of the analysis, AHP's motion as to the HMR materials should be denied, and an appropriate order entered to protect the Aventis/Andrx documents.

2. Disclosure of the Confidential Information Sought by AHP Would Result in Substantial Prejudice to Aventis and Andrx.

Many of the documents that would be responsive to AHP's broad document request are extremely sensitive. *See The Seeburg Corp.*, 1966 FTC LEXIS 230 (Oct. 25, 1966), at *8 (noting that sensitive information such as marketing strategies and technical, marketing and purchasing experiences of customers and competitors "should not be released without compelling need"). Documents describing how Aventis and Andrx prosecute and defend patent suits, assess markets, effectuate pricing strategies and otherwise compete in the marketplace are

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American Home Products Corporation's Motion to Compel at 9-11 and Ex. C.

confidential by their very nature and thus constitute information that neither company would voluntarily disclose to others, particularly to other potential competitors.

Essentially, AHP argues that the wholesale production of confidential Aventis and Andrx cannot be prejudicial because the confidentiality of the documents would be protected under the Protective Order entered in this matter.[6] AHP's response is inadequate on all fronts.

First, the production of confidential documents in this case necessarily entails the sharing of competitively sensitive information with other potential competitors — a result that unavoidably causes prejudice. Second, regardless of how the Protective Order operates here, Aventis and Andrx still possess only derivative rights through Complaint Counsel to protect their documents and otherwise challenge any overreaching on the part of the Respondent. In that their rights as a non-party are substantially less than if they were a party or the subject of proper third-party discovery, the prejudice to Aventis and Andrx in proceeding in the manner demanded by AHP's document request is manifest. Finally, to the extent that this tribunal adopts AHP's suggestion that the existence of a Protective Order is sufficient to forestall any finding of prejudice, Aventis and Andrx will be prejudiced because each of their rights to request the return of their documents at the conclusion of administrative litigation pursuant to 15 U.S.C. § 57b-2(b)(5) and 16 C.F.R. § 4.12(a)(2) is effectively nullified.

A. Regardless of the Protective Order, Aventis and Andrx are Prejudiced When Their Commercially Sensitive Documents are Shared with Potential Competitors.

AHP's contention that the existence of the Protective Order will insulate Aventis and Aventis from prejudice resulting in the improper production of sensitive documents misses the point that injecting these documents into this litigation will result in substantial prejudice.

Not only will AHP, a potential competitor of Aventis and Andrx in pharmaceuticals, have unfettered access to these documents, which include information about Aventis' and Andrx's business practices and intellectual property, but the other potential competitors of Aventis and Andrx involved in this litigation — Schering, Upsher-Smith, ESI — will have access as well.

Such unobstructed access to these confidential documents is by definition prejudicial. *See Seeburg*, 1966 FTC LEXIS 230, at *9 (making a determination that the party seeking discovery should not seek discovery from the Commission where the discovery sought is sensitive data relating to customers or competitors); *see also King v. DOJ*, 830 F.2d 210, 233 (D.C. Cir. 1987) (noting parties discussed in invetigatory files may have a strong interest in non-disclosure); *Pioneer Hi-Bred*, 105 F.R.D. at 81-82 (stating that in order to prevent unnecessary disclosure of trade secrets, federal courts will impose additional requirements of relevancy and need for the documents on the party seeking to obtain those trade secrets). The Protective Order here will not obviate the sensitive nature of these documents or the ability of AHP, Schering, Upsher-Smith, and ESI employees to sift these documents for useful information to use against their potential competitors.

It was to safeguard effectively those documents that Aventis and Andrx entered into the HMR Litigation Protective Order, which allowed the parties to disclose documents without the fear that they would be used for a purpose outside the HMR Litigation. Granting AHP's motion would effectively destroy any practical value of the HMR Litigation Protective Order and result in adverse consequences to Aventis and Andrx. Aventis and Andrx would have at best derivative rights from the FTC to protect their documents, and derivative rights from those companies who would then obtain those documents from the FTC, and who were later

[6] Neither Aventis nor Andrx are parties to this litigation, but AHP concedes that the May

faced with a document request or subpoena. The FTC's use of its subpoena power will inevitably result in the disclosure of sensitive information to multiple parties, who have a vested interest in the information beyond any litigation with which those parties may be involved.

B. Aventis and Andrx will be Prejudiced Because, as Third-Parties, They Only Possess Derivative Rights to Protect their Confidential Documents.

Under any reasonable view of the facts, a third party does not have a comparable ability to protect confidential documents as do parties to the litigation. The rights of third parties are, by definition, derivative of and therefore inferior to those of the parties. Indeed, the inferiority of third party rights are amply demonstrated by this proceeding. For example, in this instant dispute, despite the fact that the document request in question was delivered to Complaint Counsel over two months ago, Aventis and Andrx only learned of the specifics of a discovery dispute when there was less than a week to formulate the response needed to protect their documents. While Aventis and Andrx appreciate this tribunal's willingness to grant a brief extension so that their concerns might be heard, it remains that because they were not parties, Andrx and Aventis did not have the same opportunity to challenge or test the basis for this document request as would have been available to a party.

Similarly, while AHP now invites Andrx and Aventis to "designate" previously produced documents as "confidential" or "restricted confidential" under the Protective Order in this case, it ignores the fact that Complaint Counsel, not Andrx or Aventis, will decide what documents are responsive and what documents are not responsive to AHP's request. Even assuming that Complaint Counsel possesses the necessary resources that would permit it to review meaningfully tens of thousands of pages of confidential documents, Complaint Counsel

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10, 2001 Protective Order would apply to all of its document requests. *See* Resp. Mot. at 12-13.

will necessarily not be as familiar with those documents as would counsel for the companies and thus less capable of interposing appropriate discovery objections based on relevancy and scope.

C. Aventis, Andrx and Third Party Producers in the HMR Litigation Will be Prejudiced to the Extent that Confidential Information Produced in the HMR Litigation is Reproduced in Parallel Proceedings or Future FTC Proceedings.

As AHP admits in its motion, statutory authority should not be construed to prevent disclosure in adjudicative proceedings, and 16 C.F.R. 4.10(d) allows confidential documents produced to the FTC to be disclosed. *See* Resp. Mot. at 12. Thus, there is nothing to prevent all of the documents requested by AHP from being produced in a parallel proceeding resulting in further exposure of sensitive documents.[7] Nor is there anything to prevent the documents from being produced in still another future proceeding, or a future proceeding for which some or all of the documents have already been reproduced. This tribunal simply cannot ensure that this daisy chain of production of sensitive and confidential documents (produced each time under the increasingly meaningless rubric of "reasonable relevance") will ever come to an end.

Production of documents responsive to AHP's request will not only harm Andrx's and Aventis' limited control over their documents, causing prejudice as a result, it will also force Andrx and Aventis to consider the needs of other non-parties whose documents were included in the submission of documents by Andrx and Aventis to the FTC in the HMR Litigation. In order to fully comply with the HMR Litigation Protective Order, those other non-parties will require *in camera* orders or appropriate notification that their documents are to be produced, and an opportunity to object. Subsequent reproductions of these documents will repeatedly require

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[7] *See, e.g.*, In re *Cardizem CD Antitrust Litigation*, 200 F.R.D. 326 (E.D. Mich. 2001). (maintaining action on behalf of the class as redefined in multidistrict litigation)

application of the HMR Litigation Protective Order, in addition to any other protective orders for other matters, in a fair manner.

Thus, even if the documents subject to AHP's subpoena could be considered relevant to this proceeding, this tribunal should follow its own precedent and balance that purported relevance against "the rights of third parties who have complied with investigatory demands and the public interest in minimizing disclosure of confidential documents produced in investigations." HMR August 18, 2000 Order, at *13-14. In that case, Andrx's much *narrower* request for *specific* agreements among generic and innovator pharmaceutical companies was limited by this tribunal. *See id.* If AHP's motion here is granted, AHP will gain access to tens of thousands of pages of highly sensitive and proprietary information, and there is a significant risk that the documents will be the subject of discovery in parallel and subsequent proceedings that will harm not only Andrx and Aventis, but other non-parties as well. Given the extent to which the documents bear an utter lack of relevance of the information sought, this tribunal should take adequate steps to ensure that these documents are not produced on AHP's terms.

3. AHP Has Not Shown That It Could Have Sought the Information Using More Direct, Less Burdensome and Less Expensive Means

Even if one were to set aside the fact that AHP has totally failed to establish that the confidential documents produced in the HMR Litigation are somehow relevant to its claims here, as well as the fact that substantial prejudice will result if AHP's motion is granted, AHP's document request still fails because AHP has totally failed to consider — and where possible, minimize — the cost, expense and burdens that others would be forced to bear were its motion to be granted. AHP's obligation to avoid undue burdens or expenses in pursuing discovery comes from two places. First, as noted at the outset, 16 C.F.R. § 3.31(c)(1) expressly directs parties seeking discovery in Commission proceedings to take into account the cost, convenience and

burden of discovery. Second, the "substantial need" analysis noted above also appears to embrace considerations of convenience and burden. *See* HMR August 18, 2000 Order at *13-14. (holding discovery seeker entitled to relevant nonprivileged information only if it establishes "substantial need"); *see Kroger*, 1977 FTC LEXIS, at *4 ("It must be shown that the information and material being sought are not available from alternative sources"); *see also In the Matter of Hoechst Marion Roussel, Inc., Carderm Capital L.P., and Andrx Corp.*, Docket 9293, Order on Schering-Plough's Motion to Quash and Upsher-Smith's Motion to Quash, (Oct. 4, 2000), at 2 (stating it is appropriate to deny discovery in order to protect a party from, *inter alia*, undue burden or expense). Again, a problem with AHP's request is that it requires both Complaint Counsel and third parties to respond to discovery in perhaps the most inconvenient, cumbersome and expensive process imaginable.

As demonstrated *supra,* AHP offers no justifiable reason why the documents it seeks are relevant to this litigation. In light of that fact, production of the documents will have no likely benefit. In contrast, the request places burdens on Aventis and Andrx, who must now litigate their rights derivatively; on the FTC, which must review tens of thousands of pages of documents for relevance while taking adequate measures to ensure the protection of those documents; and on this tribunal, which is obligated to monitor this process. A balancing of these factors makes clear such broad discovery cannot permitted.

As set forth above, AHP could have sought the material it seeks from Complaint Counsel directly from Andrx or Aventis by means of third party subpoenas. *See, e.g.,* In re *Wheat Farmers Antitrust Class Action Litigation*, 1983 U.S. Dist. LEXIS 18788 (D.D.C. Mar. 4, 1983), at *5 (denying application for an order compelling discovery from the FTC for documents from previous investigations when "information plaintiff seeks should be available from the

defendants themselves, who should first be asked for it directly"). Had it done so, the companies would have had the opportunity to review those documents for relevance, as well as take protective measures to ensure that sensitive materials were not improperly disclosed. AHP, in turn, would have had the freedom to clarify what specific documents it required in order to gain information on what it deemed critical issues. AHP's opportunity to obtain the information sought, *see* 16 C.F.R. § 3.31(c)(1)(ii) warrants a denial of its request.

It is telling that even after it had filed its motion against Complaint Counsel, AHP served a third-party subpoena on Andrx that did not even call for production of the Andrx material AHP was at that time seeking from Complaint Counsel. Rather, AHP's requests to Andrx were limited to material concerning Andrx's generic sustained release potassium chloride product. Although Andrx believes that the material is irrelevant to this action and thus does not concede or suggest that it would provide the material to AHP if AHP were to serve a subpoena for that material, the fact that AHP did not even bother to seek it from Andrx clearly demonstrates that AHP should not be entitled to obtain it from Complaint Counsel.

The process AHP seeks will result in unreasonably cumulative and duplicative discovery. While the precise mechanism that AHP would employ to sift through tens of thousands of pages of documents is unclear, the general outline is clearly cumbersome. Apparently, AHP believes that it is possible for Aventis and Andrx to go through the tens of thousands of pages of documents that each party produced and determine whether each document would be confidential and, if so, whether any confidential document would receive a designation of "confidential" or "restricted confidential" according to the protections provided in the Protective Order. *See* Resp. Mot. at 13. Then, it would presumably fall upon Complaint Counsel to determine which of the thousands of documents were responsive to AHP's broadly

described document requests and produce logs for any documents withheld. *Id.* (It does not appear that Andrx or Aventis would have any right to participate in that process). Given that the documents AHP seeks are available through alternative methods from the parties that could produce the documents more efficiently than the FTC, such a process would undermine the standards laid out at 16 C.F.R. § 3.31(c)(1)(i).

As a result of AHP's document request, the FTC has retained the documents produced in the HMR Litigation, at least until this matter is resolved. Neither Andrx nor Aventis has the ability to focus the discovery on documents that are truly relevant, or to notify the proper nonparties whose documents had contributed to the HMR Litigation production. The potential cost of such an overbroad production will go beyond the production of nonrelevant documents. Such a production will enhance the opportunities for these documents to be produced and reproduced down the line in parallel and subsequent litigation, and for concomitant proceedings to occur to safeguard the rights of the numerous nonparties who will seek to protect the sensitivity of their documents. For these reasons, AHP's document requests must be denied.

III. CONCLUSION

For the foregoing reasons, Andrx and Aventis respectfully request that this tribunal grant a protective order precluding the production of documents produced to the FTC in the *The Matter of Hoechst Marion Roussel, Inc. Docket No. 9293* to Respondent American Home Products.

Dated: August 9, 2001

Respectfully submitted,

James M. Spears
Jeffrey Pearlman
Ropes & Gray
1301 K Street, N.W.
Suite 800 East
Washington, DC 20005
(202) 626-3981
Attorneys for Aventis Pharmaceuticals Inc.

Colin Underwood by

Louis M. Solomon
Colin A. Underwood
Solomon, Zauderer, Ellenhorn, Frischer & Sharp
45 Rockefeller Plaza
7th Floor
New York, New York 10111
(212) 956-3700
Attorneys for Andrx Pharmaceuticals, Inc.

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

In the Matter of	)	
Schering-Plough Corporation, a corporation,	)	Docket No. 9297
Upsher-Smith Laboratories, a corporation,	)	
and	)	
American Home Products Corporation, a corporation.	)	

CERTIFICATE OF SERVICE

I, James M. Spears, hereby certify that on August 9, 2001, I caused a true and correct copy of ANDRX PHARMACEUTICAL, INC.'S AND AVENTIS PHARMACEUTICAL INC.'S JOINT MOTION FOR A PROTECTIVE ORDER PRECLUDING THE PRODUCTION OF DOCUMENTS AND MATERIALS PRODUCED IN *IN THE MATTER OF HOECHST MARION ROUSSEL, INC.*, DOCKET NO. 9293 TO RESPONDENT AMERICAN HOME PRODUCTS CORPORATION to be served upon the following persons by hand delivery and facsimile:

Hon. D. Michael Chappell
Administrative Law Judge
Federal Trade Commission
Room 104
600 Pennsylvania Avenue, N.W.
Washington, DC 20580 (2 copies)

Office of the Secretary
Federal Trade Commission
Room H-159
600 Pennsylvania Avenue, N.W.
Washington, DC 20580 (1 copy)

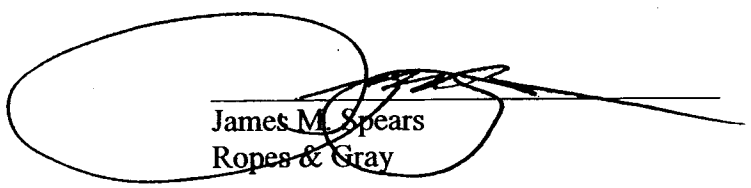
Richard A. Feinstein
Assistant Director, Bureau of Competition
Federal Trade Commission
Room 3114
601 Pennsylvania Avenue, N.W.
Washington, DC 20580

Karen G. Bokat
Federal Trade Commission
601 Pennsylvania Avenue, N.W.
Room 3115
Washington, DC 20580
Fax (202) 326-3384

Robert Paul
Christopher Curran
White & Case LLP
601 Thirteenth Street, N.W.
Washington, DC 20005
Fax (202) 639-9355

Laura S. Shores
Howrey Simon Arnold & White LLP
1299 Pennsylvania Avenue, N.W.
Washington, DC 20004
Fax (202) 383-6610

Michael N. Sohn
Cathy A. Hoffman
David M. Orta
Barbara H. Wootton
Arnold & Porter
555 Twelfth Street, N.W.
Washington, DC 20004
Fax (202) 942-5999



James M. Spears
Ropes & Gray

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

In the Matter of	)	
Schering-Plough Corporation, a corporation,	)	Docket No. 9297
Upsher-Smith Laboratories, a corporation,	)	
and	)	
American Home Products Corporation, a corporation.	)	

DECLARATION OF JAMES M. SPEARS IN SUPPORT OF ANDRX PHARMACEUTICAL, INC.'S AND AVENTIS PHARMACEUTICAL INC.'S JOINT MOTION FOR A PROTECTIVE ORDER PRECLUDING THE PRODUCTION OF DOCUMENTS AND MATERIALS PRODUCED IN *IN THE MATTER OF HOECHST MARION ROUSSEL, INC.*, DOCKET NO. 9293 TO RESPONDENT AMERICAN HOME PRODUCTS CORPORATION

I, James M. Spears, pursuant to 28 U.S.C. § 1746, declare as follows:

1. I am associated with the firm of Ropes & Gray, counsel for respondent Aventis Pharmaceuticals Inc. ("Aventis").

2. On or about July 25, 2001, Aventis received copies of Respondent American Home Products Corporation's ("AHP") July 23, 2001 Motion to Compel Complaint Counsel ("Resp. Mot.") to Search the Federal Trade Commission for Responsive Documents, which also contained a copy of the original documents request, Complaint Counsel's Objections and Responses dated June 25, 2001, as well as the other documents filed by Respondent AHP in support of its motion. It was my understanding from conversations with Complaint Counsel that a documents request affecting Aventis and Andrx had been filed by AHP, but Aventis was never served a copy of this request, contacted by AHP with respect to this request, or given a copy of this request prior to July 23, 2001.

3. Aventis have never entered into an agreement or otherwise engaged in any conduct which might preclude or delay anyone from entering a market for sustained release potassium chloride.

4. Annexed hereto as Attachment A is a copy of Counsel for Aventis' May 17, 2001 letter in behalf of Aventis requesting the return of documents produced as part of *In the Matter of Hoecht Marion Roussel, Inc.* Docket No. 9392 ("HMR" or "HMR Litigation").

5. Annexed hereto as Attachment B is a copy of the April 28, 2000 Protective Order in the HMR Litigation.

6. Aventis documents responsive to AHP's document request contain confidential and proprietary business information, as well as trade secrets of Aventis. Some of the documents describe how Aventis prosecutes and defends patent suits, assesses markets, effectuates pricing strategies and otherwise competes in the marketplace. Some of the documents contain confidential information belonging to third parties and are subject to protective orders issued in litigation involving Aventis and said third parties.

7. The production of all Aventis documents responsive to AHP's request would require the review of at least 38,000 pages of documents.

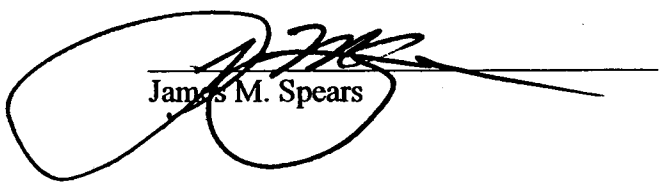
8. As of this date, AHP has not contacted Aventis in order to request access to any documents that it alleges are relevant to this litigation, or served Aventis with third-party discovery with respect to any such documents.

9. The litigation between Aventis and Andrx settled without any licensing provisions. No royalties were ever paid in connection with the settlement of that litigation.

I declare under the penalty of perjury that the foregoing is true and correct.

Executed in Washington, D.C., on August 9, 2001

Respectfully Submitted,



James M. Spears

A

ROPES & GRAY
ONE FRANKLIN SQUARE
1301 K STREET, N.W.
SUITE 800 EAST
WASHINGTON, DC 20005-3333
(202) 626-3900
FAX: (202) 626-3961

ONE INTERNATIONAL PLACE
BOSTON, MA 02110-2624
(617) 951-7000
FAX: (617) 951-7050

30 KENNEDY PLAZA
PROVIDENCE, RI 02903-2328
(401) 455-4400
FAX: (401) 455-4401

WRITER'S DIRECT DIAL NUMBER: (202) 626-3981
WRITER'S E-MAIL ADDRESS: JSPEARS@ROPESGRAY.COM

May 17, 2001

Bradley Albert, Esq.
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, DC 20580

Re: Request for Return of Documents Submitted to Commission

Dear Brad:

This letter confirms our phone conversation of Tuesday concerning the return of all documents and other materials provided to the Commission for the Hoechst-Andrx investigation (FTC File No. 981-0368, Docket No. 9293). Pursuant to the provisions of the applicable statute and regulations, 15 U.S.C. § 57b-2(b)(5) and 16 C.F.R. § 4.12, we hereby formally request that you return to me at the above address, all materials submitted to the Commission by my client, Hoechst Marion Roussel, Inc., now known as Aventis Pharmaceuticals, Inc, during the course of that investigation and administrative litigation and any copies thereof that may have been made of the submitted materials by the Commission or any of its agents or employees.

When the return of these documents is completed, we would appreciate receiving from you a description of any documents that may have been retained by the Commission and the legal basis supporting such retention.

Thank you for your prompt attention to this request.

Sincerely yours,

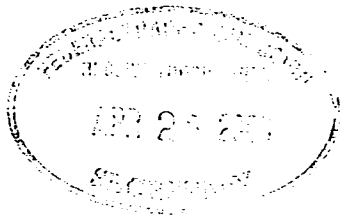
James M. Spears

JMS:mjf:7108864.1

B

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

In the Matter of HOECHST MARION ROUSSEL, INC., a corporation, CARDERM CAPITAL L.P., a limited partnership, and ANDRX CORPORATION, a corporation.	Docket No. 9293



PROTECTIVE ORDER GOVERNING DISCOVERY MATERIAL

For the purpose of protecting the interests of the parties and third parties in the above-captioned matter (the "Matter") against improper use and disclosure of confidential information submitted or produced in connection with this Matter:

IT IS HEREBY ORDERED THAT this Protective Order Governing Confidential Material ("Protective Order") shall govern the handling of all Discovery Material, as hereafter defined.

DEFINITIONS

1. "Matter" means the matter captioned *In the Matter of Hoechst Marion Roussel, Inc., Carderm Capital L.P., and Andrx Corporation,* Docket Number 9293, pending before the Federal Trade Commission, and all subsequent appellate or other review proceedings related thereto.

2. "Commission" or "FTC" means the Federal Trade Commission, or any of its employees, agents, attorneys, and all other persons acting or purporting to act on its behalf,

excluding persons retained as consultants or experts for purposes of this Matter.

3. "HMR" means Aventis Pharmaceuticals Inc., formerly known as Hoechst Marion Roussel, Inc., a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business located at Parsippany, New Jersey.

4. "Carderm" means Carderm Capital L.P., a limited partnership organized, existing, and doing business under and by virtue of the laws of the Delaware, with its office and principal place of business located at Hamilton, Bermuda.

5. "Andrx" means Andrx Corporation, a corporation organized, existing, and doing business under and by virtue of the laws of the State of Florida, with its office and principal place of business located at Fort Lauderdale, Florida.

6. "Party" means either the FTC, HMR, Carderm or Andrx.

7. "Respondents" means HMR, Carderm and Andrx.

8. "Outside Counsel" means the law firm(s) that is/are counsel of record for Respondents in this Matter and its/their associated attorneys; persons regularly employed by such law firm(s) (including legal assistants, clerical staff, and information management personnel) and temporary personnel retained by such law firm(s) to perform legal or clerical duties, or to provide logistical litigation support with regard to this Matter; provided that any attorney associated with Outside Counsel shall not be a director, officer or employee of Respondents. The term Outside Counsel does not include persons retained as consultants or experts for the purposes of this Matter.

9. "Producing Party" means a Party or Third Party that produced or intends to produce Confidential Discovery Material to any of the Parties. For purposes of Confidential Discovery Material of a Third Party that either is in the possession, custody or control of the FTC or has been produced by the FTC in this Matter, the Producing Party shall mean the Third Party that originally provided the Confidential Discovery Material to the FTC. The Producing Party shall also mean the FTC for purposes of any document or material prepared by, or on behalf of the FTC.

10. "Third Party" means any natural person, partnership, corporation, association, or other legal entity not named as a party to this Matter -- including without limitation Biovail Corporation ("Biovail") and Faulding Inc. ("Faulding") -- and their employees, directors, officers, attorneys and agents.

11. "Expert/Consultant" means experts or other persons who are retained to assist complaint counsel or Respondents' counsel in preparation for trial or to give testimony at trial.

12. "Document" means the complete original or a true, correct and complete copy and any non-identical copies of any written or graphic matter, no matter how produced, recorded, stored or reproduced, including, but not limited to, any writing, letter, envelope, telegraph meeting minute, memorandum statement, affidavit, declaration, book, record, survey, map, study, handwritten note, working paper, chart, index, tabulation, graph, tape, data sheet, data processing card, printout, microfilm, index, computer readable media or other electronically stored data, appointment book, diary, diary entry, calendar, desk pad, telephone message slip, note of interview or communication or any other data compilation, including all drafts of all such documents. "Document" also includes every writing, drawing, graph, chart, photograph, phono

record, tape and other data compilations from which information can be obtained, and includes all drafts and all copies of every such writing or record that contain any commentary, notes, or marking whatsoever not appearing on the original.

13. "Discovery Material" includes without limitation deposition testimony, deposition exhibits, interrogatory responses, admissions, affidavits, declarations, documents produced pursuant to compulsory process or voluntarily in lieu thereof, and any other documents or information produced or given to one Party by another Party or by a Third Party in connection with discovery in this Matter.

14. "Confidential Discovery Material" means all Discovery Material that is designated by a Producing Party as confidential and that is covered by Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. § 46(f), and Commission Rule of Practice § 4.10(a)(2), 16 C.F.R. § 4.10(a)(2); submitted to the FTC pursuant to the Hart-Scott-Rodino Antitrust Improvements Act of 1976, 15 U.S.C. § 18a, or formal interpretations or rules promulgated thereunder, 16 C.F.R. Part 800; or Section 26(c)(7) of the Federal Rules of Civil Procedure and precedents thereunder. Confidential Discovery Material shall include non-public commercial information, the disclosure of which to Respondent or Third Parties would cause substantial commercial harm or personal embarrassment to the disclosing party. The following is a non-exhaustive list of examples of information that likely will qualify for treatment as Confidential Discovery Material: strategic plans (involving pricing, marketing, research and development, product roadmaps, corporate alliances, or mergers and acquisitions) that have not been fully implemented or revealed to the public; trade secrets; customer-specific evaluations or data (e.g., prices, volumes, or revenues); personnel files and evaluations; information subject to

confidentiality or non-disclosure agreements; proprietary technical or engineering information; proprietary financial data or projections; and proprietary consumer, customer or market research or analyses applicable to current or future market conditions, the disclosure of which could reveal Confidential Discovery Material.

TERMS AND CONDITIONS OF PROTECTIVE ORDER

1. Discovery Material, or information derived therefrom, shall be used solely by the Parties for purposes of this Matter, and shall not be used for any other purpose, including without limitation any business or commercial purpose. The Parties, in conducting discovery from Third Parties, shall attach to such discovery requests a copy of this Protective Order and a cover letter that will apprise such Third Parties of their rights hereunder.

2. Discovery Material may be designated as Confidential Discovery Material by Producing Parties by placing on or affixing, in such manner as will not interfere with the legibility thereof, the notation "CONFIDENTIAL - FTC Docket No. 9293" (or other similar notation containing a reference to this Matter) to the first page of a document containing such Confidential Discovery Material, or, by Parties by instructing the court reporter to denote each page of a transcript containing such Confidential Discovery Material as "Confidential." Such designations shall be made within fourteen (14) days from the initial production or deposition and constitute a good-faith representation by counsel for the Party or Third Party making the designations that the document constitutes or contains "Confidential Discovery Material."

3. To the extent any such material is made part of this proceeding, all documents heretofore obtained by compulsory process or voluntarily from any Party, regardless of whether

designated confidential by the Party, and transcripts of any investigational hearings, interviews and depositions, which were obtained during the pre-complaint stage of this Matter shall be treated as Confidential Discovery Material. Material previously produced by Respondents and designated as a "Confidential," regardless of whether such materials have been marked in accordance with paragraph 2 above, shall be treated as Confidential Discovery Material as provided herein. The material referred to in this paragraph shall only be available for use in this proceeding once an independent basis has been demonstrated for such use.

4. Confidential Discovery Material shall not, directly or indirectly, be disclosed or otherwise provided to anyone except, in accordance with paragraphs 5 and 6, to:

(a) complaint counsel and the Commission, as permitted by the Commission's Rules of Practice;

(b) Outside Counsel;

(c) Experts/Consultants;

(d) witnesses or deponents at trial or deposition;

(e) the Administrative Law Judge and personnel assisting him;

(f) court reporters and deposition transcript reporters;

(g) judges and other court personnel of any court having jurisdiction over any appeal proceedings involving this Matter; and

(h) any author or recipient of Confidential Discovery Material (as indicated on the face of the document, record or material), and any individual who was in the direct chain of supervision of the author at the time the Confidential Discovery Material was created or received.

5. In addition to the above-designated persons, certain named designated

individuals and in-house counsel not to exceed two attorneys per corporate party who do not have day to day business responsibilities shall be provided with access on the condition that each such in-house counsel or designated executive signs a declaration in the form attached hereto as Exhibit "A," which is incorporated herein by reference. For Respondent Carderm, the designated individual is Stephan Petri. For Respondent HMR, the designated individual is Edward Stratemeier, Vice President and General Counsel. For Respondent Andrx, the designated individual is Scott Lodin, Vice President and General Counsel.

6. Confidential Discovery Material shall not, directly or indirectly, be disclosed or otherwise provided to an Expert/Consultant unless such Expert/Consultant agrees in writing:

(a) to maintain such Confidential Discovery Material in separate locked room(s) or locked cabinet(s) when such Confidential Discovery Material is not being reviewed;

(b) to return such Confidential Discovery Material to complaint counsel or Respondent's Outside Counsel, as appropriate, upon the conclusion of the Expert/Consultant's assignment or retention;

(c) to not disclose such Confidential Discovery Material to anyone, except as permitted by the Protective Order; and

(d) to use such Confidential Discovery Material and the information contained therein solely for the purpose of rendering consulting services to a Party to this Matter, including providing testimony in judicial or administrative proceedings arising out of this Matter.

7. This paragraph governs the procedures for the following specified disclosures and challenges to designations of confidentiality.

(a) Disclosure to Experts

If any Party desires to disclose Confidential Discovery Material to any expert who may testify, who is not an FTC employee, and who may have interests in the pharmaceutical industry beyond their employment as an expert in this Matter, the disclosing Party shall notify the Producing Party of its desire to disclose such material. Such notice shall identify the specific expert who may testify to whom the Confidential Discovery Material is to be disclosed. Such identification shall include, but not be limited to, the full name and professional address and/or affiliation of the proposed expert who may testify, and a current curriculum vitae of such expert identifying all other present and prior employers and/or firms in the pharmaceutical industry for which or on behalf of which the identified expert has been employed or done consulting work in the preceding four (4) years. The Producing Party may object to the disclosure of the Confidential Discovery Material within five (5) business days of receiving notice of an intent to disclose the Confidential Discovery Material to the identified expert by providing the disclosing Party with a written statement of the reasons for the objection. If the Producing Party timely objects, the disclosing Party shall not disclose the Confidential Discovery Material to the identified expert, absent a written agreement with the Producing Party or order of the Administrative Law Judge. The Producing Party lodging an objection and the disclosing Party shall meet and confer in good faith in an attempt to determine the terms of disclosure to the identified expert. If at the end of five (5) business days of negotiating the parties have not resolved their differences or if counsel determine in good faith that negotiations have failed, the disclosing Party may make written application to the Administrative Law Judge as provided by paragraph 7(c) of this Protective Order. If the Producing Party does not object to the disclosure of Confidential Discovery Material to the identified expert within five (5) business days, the

disclosing Party may disclose the Confidential Discovery Material to the identified expert.

(b) Challenges to Confidentiality Designations

If any Party seeks to challenge a Producing Party's designation of material as Confidential Discovery Material or any other restriction contained within this Protective Order, the challenging Party shall notify the Producing Party and all Parties of the challenge to such designation. Such notice shall identify with specificity (i.e., by document control numbers, deposition transcript page and line reference, or other means sufficient to locate easily such materials) the designation being challenged. The Producing Party may preserve its designation within five (5) business days of receiving notice of the confidentiality challenge by providing the challenging Party and all Parties with a written statement of the reasons for the designation. If the Producing Party timely preserves its rights, the Parties shall continue to treat the challenged material as Confidential Discovery Material, absent a written agreement with the Producing Party or order of the Administrative Law Judge. The Producing Party preserving its rights and the challenging Party shall meet and confer in good faith in an attempt to negotiate changes to any challenged designation. If at the end of five (5) business days of negotiating the parties have not resolved their differences or if counsel determine in good faith that negotiations have failed, the challenging Party may make written application to the Administrative Law Judge as provided by paragraph 7(c) of this Protective Order. If the Producing Party does not preserve its rights within five (5) business days, the challenging Party may alter the designation as contained in the notice. The challenging Party shall notify the Producing Party and the other Party of any changes in confidentiality designations.

Regardless of confidential designation, copies of published magazine or

newspaper articles, and excerpts from published books and public documents filed with the Securities and Exchange Commission may be used by any Party without reference to the procedures of this subparagraph.

(c) Resolution of Disclosure or Confidentiality Disputes

If negotiations under subparagraphs 7(a)-(b) of this Protective Order have failed to resolve the issues, a Party seeking to disclose Confidential Discovery Material or challenging a confidentiality designation or any other restriction contained within this Protective Order may make written application to the Administrative Law Judge for relief. Such application shall be served on the Producing Party and the other Party, and be accompanied by a certification that the meet and confer obligations of this paragraph have been met, but that good faith negotiations have failed to resolve outstanding issues. The Producing Party and any other Party shall have five (5) business days to respond to the application, which time may be extended by the Administrative Law Judge. While an application is pending, the Parties shall maintain the pre-application status of the Confidential Discovery Material. Nothing in this Protective Order shall create a presumption or alter the burden of persuading the Administrative Law Judge of the propriety of a requested disclosure or change in designation.

8. Confidential Discovery Material shall not be disclosed to any person described in subparagraphs 4(b), 4(c) and 4(d) and paragraph 5 of this Protective Order until such person has executed and transmitted to Respondent's counsel or complaint counsel, as the case may be, a declaration or declarations, as applicable, in the form attached hereto as Exhibit "A," which is incorporated herein by reference. Respondents' counsel and complaint counsel shall maintain a file of all such declarations for the duration of the litigation. Confidential Discovery Material

shall not be copied or reproduced for use in this Matter except to the extent such copying or reproduction is reasonably necessary to the conduct of this Matter, and all such copies or reproductions shall be subject to the terms of this Protective Order. If the duplication process by which copies or reproductions of Confidential Discovery Material are made does not preserve the confidentiality designations that appear on the original documents, all such copies or reproductions shall be stamped "CONFIDENTIAL - FTC Docket No. 9293."

9. The Parties shall not be obligated to challenge the propriety of any designation or treatment of information as confidential and the failure to do so promptly shall not preclude any subsequent objection to such designation or treatment, or any motion seeking permission to disclose such material to persons not referred to in paragraphs 4 and 5 above. If Confidential Discovery Material is produced without the legend attached, such document shall be treated as Confidential from the time the Producing Party advises complaint counsel and Respondents' counsel in writing that such material should be so designated and provides all the Parties with an appropriately labeled replacement. The Parties shall return promptly or destroy the unmarked documents.

10. If the FTC: (a) receives a discovery request that may require the disclosure by it of a Third Party's Confidential Discovery Material; or (b) intends to or is required to disclose, voluntarily or involuntarily, a Third Party's Confidential Discovery Material (whether or not such disclosure is in response to a discovery request), the FTC promptly shall notify the Third Party of either receipt of such request or its intention to disclose such material. Such notification shall be in writing and, if not otherwise done, sent for receipt by the Third Party at least five (5) business days before production, and shall include a copy of this Protective Order and a cover letter that

will apprise the Third Party of its rights hereunder.

11. If anyone receives a discovery request in another proceeding that may require the disclosure of a Producing Party's Confidential Discovery Material, the subpoena recipient promptly shall notify the Producing Party of receipt of such request. Such notification shall be in writing and, if not otherwise done, sent for receipt by the Producing Party at least five (5) business days before production, and shall include a copy of this Protective Order and a cover letter that will apprise the Producing Party of its rights hereunder. The Producing Party shall be solely responsible for asserting any objection to the requested production. Nothing herein shall be construed as requiring the subpoena recipient or anyone else covered by this Order to challenge or appeal any such order requiring production of Confidential Discovery Material, or to subject itself to any penalties for noncompliance with any such order, or to seek any relief from the Administrative Law Judge or the Commission.

12. This Order governs the disclosure of information during the course of discovery and does not constitute an *in camera* order as provided in Section 3.45 of the Commission's Rules of Practice ("Rule"), 16 C.F.R. § 3.45.

13. (a) The Commission's Rules of Practice require that material may not be withheld from the public record unless it falls within the scope of an order by the Administrative Law Judge that such material, or portions thereof, be placed *in camera*. 16 C.F.R. § 3.45(b) and (d). To comply with this rule, the Party seeking to introduce into evidence by filing a pleading, an exhibit thereto, or otherwise placing on the record Confidential Discovery Material ("filing Party") must first obtain an order by the Administrative Law Judge that such information has been granted *in camera* status.

An application for *in camera* treatment must: (1) specifically identify or describe the materials for which *in camera* treatment is sought; (2) provide reasons for granting such materials *in camera* status; (3) specify the time period for which *in camera* treatment is sought for each document; and (4) attach as exhibits to the application the documents containing the specific information for which *in camera* treatment is sought.

A blanket *in camera* order for an entire pleading is contrary to public policy and will not be granted. The parties must specifically identify the portions of a pleading, document, deposition transcript, or exhibit for which *in camera* treatment is sought. Entire documents or exhibits will rarely, if ever, be eligible for *in camera* treatment. The parties are reminded that Rule 3.45 places the burden of showing that public disclosure will likely result in a clearly defined, serious injury upon the person requesting *in camera* treatment. In addition, to sustain the burden of proof, an application must be supported by proper evidence, such as affidavits, to support all factual issues. *See* 16 C.F.R. § 3.43.

(b) The Scheduling Order requires the parties to file motions to request *in camera* treatment of materials marked confidential pursuant to a protective order no later than September 1, 2000.

A Party that has produced materials or information that it reasonably expects to include in a pleading, motion, exhibit or other paper to be filed with the Secretary ("pleading") and that it believes meets the standards for *in camera* treatment must file a motion with the Administrative Law Judge to request *in camera* treatment of such materials no later than September 1, 2000.

A Party that has received materials or information from another Party or a

Third Party that it reasonably expects to include in a pleading must provide the opposing Party or Third Party with a list of such materials no later than August 18, 2000. A Third Party shall be provided with a copy of this Order along with such list. This list will not be filed with the Secretary's Office, but must be served on the Administrative Law Judge.

(c) If any Party seeks to introduce into evidence, by filing a pleading or otherwise placing on the record, information which includes its own Confidential Discovery Material which has not previously been granted *in camera* status, and the Party seeks to prevent its own materials or information from being placed on the public record, at least 10 days prior to filing such pleading, -- unless it is impracticable (e.g., when filing a response or reply brief) in which case at least 5 days prior to filing such pleading -- the Party shall make an application to the Administrative Law Judge to request that such materials or information be treated as *in camera* information.

If any Party seeks to introduce into evidence, by filing a pleading or otherwise placing on the record, information which includes another Party's Confidential Discovery Material which has not previously been granted *in camera* status, the filing Party must notify the other Party's counsel at least 14 days prior to such proposed filing -- unless it is impracticable (e.g., when filing a response or reply brief). If 14 days advance notice cannot be provided, the other Party's counsel must be notified as soon as possible and prior to the time of introduction of such documents or information. The Producing Party's counsel shall have 7 days from the date of notice to make an application to the Administrative Law Judge to request that such materials be treated as *in camera* information. The parties shall not file pleadings or attachments thereto that contain another Party's Confidential Discovery Material unless the Party

seeking to introduce such material has first obtained an *in camera* order or certifies that the other Party has been given proper notice prior to the introduction of such material.

The parties shall not file pleadings or attachments thereto that contain a Third Party's Confidential Discovery Material unless the Party seeking to introduce such material has first obtained an *in camera* order or certifies that the Third Party has been given 14 days notice prior to the introduction of such material and a copy of this Order.

(d) The parties are cautioned that compliance with this Order will require them to submit applications for *in camera* treatment in advance of filing motions which include confidential materials and that deadlines for filing motions attaching confidential materials will not be extended for failure to file applications for *in camera* treatment in a timely manner. The parties are further cautioned that it is rarely necessary to attach confidential information in support of pleadings. Absent strict adherence to these procedures, pleadings should be composed in a manner which sufficiently apprises the Court of the matter at issue and which does not identify or disclose any confidential information. Failure to comply with these procedures may result in pleadings or portions thereof being stricken from the record.

14. Nothing in this Protective Order shall be construed to conflict with the provisions of Sections 6, 10, and 21 of the Federal Trade Commission Act, 15 U.S.C. §§ 46, 50, 57b-2, or with Rules 3.22, 3.45 or 4.11(b)-(e), 16 C.F.R. §§ 3.22, 3.45 and 4.11(b)-(e).[1] Any Party or Producing Party may move at any time for, treatment *in camera* of any Confidential

[1] The right of the Administrative Law Judge, the Commission, and reviewing courts to disclose information afforded *in camera* treatment or Confidential Discovery Material, to the extent necessary for proper disposition of the proceeding, is specifically reserved pursuant to Rule 3.45, 16 C.F.R. § 3.45.

Discovery Material or any portion of the proceedings in this Matter to the extent necessary for proper disposition of the Matter.

15. At the conclusion of this Matter, Respondent's counsel shall return to the Producing Party, or destroy, all originals and copies of documents and all notes, memoranda, or other papers containing Confidential Discovery Material which have not been made part of the record in this Matter. Complaint counsel shall dispose of all documents in accordance with Rule 4.12, 16 C.F.R. § 4.12.

16. The provisions of this Protective Order, insofar as they restrict the communication and use of Confidential Discovery Material shall, without written permission of the Producing Party or further order of the Administrative Law Judge hearing this Matter, continue to be binding after the conclusion of this Matter.

17. This Protective Order shall not apply to the disclosure by a Producing Party or its Counsel of such Producing Party's Confidential Discovery Material to such Producing Party's employees, agents, former employees, board members, directors, and officers.

18. The production or disclosure of any Discovery Material made after entry of this Protective Order which a Producing Party claims was inadvertent and should not have been produced or disclosed because of a privilege will not automatically be deemed to be a waiver of any privilege to which the Producing Party would have been entitled had the privileged Discovery Material not inadvertently been produced or disclosed. In the event of such claimed inadvertent production or disclosure, the following procedures shall be followed:

(a) The Producing Party may request the return of any such Discovery Material within twenty (20) days of discovering that it was inadvertently produced or disclosed

(or inadvertently produced or disclosed without redacting the privileged content). A request for the return of any Discovery Material shall identify the specific Discovery Material and the basis for asserting that the specific Discovery Material (or portions thereof) is subject to the attorney-client privilege or the work product doctrine and the date of discovery that there had been an inadvertent production or disclosure.

(b) If a Producing Party requests the return, pursuant to this paragraph, of any such Discovery Material from another Party, the Party to whom the request is made shall return immediately to the Producing Party all copies of the Discovery Material within its possession, custody, or control – including all copies in the possession of experts, consultants, or others to whom the Discovery Material was provided – unless the Party asked to return the Discovery Material in good faith reasonably believes that the Discovery Material is not privileged. Such good faith belief shall be based on either (i) a facial review of the Discovery Material, or (ii) the inadequacy of any explanations provided by the Producing Party, and shall not be based on an argument that production or disclosure of the Discovery Material waived any privilege. In the event that only portions of the Discovery Material contain privileged subject matter, the Producing Party shall substitute a redacted version of the Discovery Material at the time of making the request for the return of the requested Discovery Material.

(c) Should the Party contesting the request to return the Discovery Material pursuant to this paragraph decline to return the Discovery Material, the Producing Party seeking return of the Discovery Material may thereafter move for an order compelling the return of the Discovery Material. In any such motion, the Producing Party shall have the burden of showing that the Discovery Material is privileged and that the production was inadvertent.

19. Entry of the foregoing Protective Order is without prejudice to the right of the Parties to apply for further protective orders or for modification of any provision of this Protective Order.

ORDERED:

D. Michael Chappell
Administrative Law Judge

Dated: April 28, 2000

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

EXHIBIT A

In the Matter of HOECHST MARION ROUSSEL, INC., a corporation, CARDERM CAPITAL L.P., a limited partnership, and ANDRX CORPORATION, a corporation.	Docket No. 9293

DECLARATION CONCERNING PROTECTIVE ORDER GOVERNING DISCOVERY MATERIAL

I, [NAME], hereby declare and certify the following to be true:

1. [Statement of employment]

2. I have read the "Protective Order Governing Discovery Material" ("Protective Order") issued by Administrative Law Judge D. Michael Chappell on April 28, 2000, in connection with the above captioned matter. I understand the restrictions on my use of any Confidential Discovery Material (as this term is used in the Protective Order) in this action and I agree to abide by the Protective Order.

3. I understand that the restrictions on my use of such Confidential Discovery Material include:

   a. that I will use such Confidential Discovery Material only for the purposes of preparing for this proceedings, and hearing(s) and any appeal of this proceeding and for no other purpose;

   b. that I will not disclose such Confidential Discovery Material to anyone, except as permitted by the Protective Order; and

c. that upon the termination of my participation in this proceeding I will promptly return all Confidential Discovery Material, and all notes, memoranda, or other papers containing Confidential Discovery Material, to complaint counsel or respondent's counsel, as appropriate.

[4. I understand that if I am receiving Confidential Discovery Material as an Expert/Consultant, as that term is defined in this Protective Order, the restrictions on my use of Confidential Discovery Material also include the duty and obligation:

a. to maintain such Confidential Discovery Material in separate locked room(s) or locked cabinet(s) when such Confidential Discovery Material is not being reviewed;

b. to return such Confidential Discovery Material to complaint counsel or Respondent's Outside Counsel, as appropriate, upon the conclusion of my assignment or retention; and

c. to use such Confidential Discovery Material and the information contained therein solely for the purpose of rendering consulting services to a Party to this Matter, including providing testimony in judicial or administrative proceedings arising out of this Matter.]

5. I am fully aware that, pursuant to Section 3.42(h) of the Commission's Rules of Practice, 16 C.F.R. § 3.42(h), my failure to comply with the terms of the Protective Order may constitute contempt of the Commission and may subject me to sanctions imposed by the Commission.

Date: _____

_____

Full Name [Typed or Printed]

_____

Signature

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

In the Matter of	)	
	)	
Schering-Plough Corporation, a corporation,	)	Docket No. 9297
	)	
Upsher-Smith Laboratories, a corporation,	)	
	)	
and	)	
	)	
American Home Products Corporation, a corporation.	)	

DECLARATION OF COLIN A. UNDERWOOD IN SUPPORT OF JOINT MOTION OF ANDRX PHARMACEUTICAL, INC. AND AVENTIS PHARMACEUTICALS INC. FOR A PROTECTIVE ORDER PRECLUDING THE PRODUCTION OF DOCUMENTS AND MATERIALS PRODUCED IN *IN THE MATTER OF HOECHST MARION ROUSSEL, INC.*, DOCKET NO. 9293, TO RESPONDENT AMERICAN HOME PRODUCTS CORPORATION

I, Colin A. Underwood, pursuant to 28 U.S.C. § 1746, declare as follows:

1. I am a member of Solomon, Zauderer, Ellenhorn, Frischer & Sharp, counsel for movant Andrx Pharmaceuticals, Inc. ("Andrx").

2. During the course of the pre-complaint investigation and litigation of *In the Matter of Hoecht Marion Roussel, Inc.* Docket No. 9392 ("HMR" or "HMR Litigation"), Andrx produced over 170,000 pages of material to FTC. The great majority of those documents contain confidential and proprietary business information, as well as trade secrets of Andrx, including information concerning how Andrx develops, prices and markets its products. Some of the documents produced by Andrx contain confidential information belonging to third parties and subject to confidentiality agreements or protective orders issued in other litigation. All of this material was covered by the April 28, 2000 Protective Order entered in the HMR Litigation (attached as Attachment B to the accompanying Declaration of James M. Spears).

3. The HMR Litigation was finally resolved in April 2001. During May 2001, I spoke several times with FTC counsel Bradley S. Albert concerning the return of documents produced by Andrx as part of the HMR Litigation. Mr. Albert agreed to deliver all of the Andrx documents to me. On June 7, 2001, Mr. Albert informed me that because Complaint Counsel had received a document request in this proceeding that arguably could be read to cover the Andrx documents in FTC's possession, he would not be able to send the documents back to

Andrx pending a determination of whether Complaint Counsel would need to produce the documents in this proceeding. I asked Mr. Albert to send me a copy of the document request that FTC believed covered the Andrx documents but he told me that the request was not public and he was not sure that he could send it to me.

4. On or about July 25, 2001, Andrx received copies of the July 23, 2001 Motion of Respondent American Home Products Corporation ("AHP") to Compel Complaint Counsel to Search the Federal Trade Commission for Responsive Documents ("AHP Mot."), which also contained a copy of AHP's original document request dated June 1, 2001, Complaint Counsel's Objections and Responses dated June 25, 2001, as well as the other documents filed by Respondent AHP in support of its motion. Prior to July 25, 2001, Andrx had not seen AHP's request or Complaint Counsel's response.

5. Andrx has filed an Abbreviated New Drug Application ("ANDA") seeking permission to market a generic sustained release potassium chloride product and has never entered into an agreement or otherwise engaged in any conduct which might preclude or delay anyone else from marketing such a product.

6. During the course of the pre-complaint investigation in connection with this action, Andrx produced over 5500 pages of material in response to requests from Complaint Counsel. I understand that all of that material has been disclosed to the parties to this action.

7. On July 27, 2001, AHP served Andrx with a subpoena duces tecum seeking further material from Andrx in connection with this action ("AHP subpoena"). A copy of that subpoena is attached hereto as Attachment A. Although that subpoena was served after AHP had filed its motion against Complaint Counsel, AHP did not even bother to request from Andrx the Andrx documents it is seeking from Complaint Counsel. Rather, the AHP subpoena seeks only documents limited to Andrx's activities and plans concerning a 20 mEq potassium chloride product. Virtually all of the documents produced by Andrx in the HMR Litigation are *not* responsive to the AHP subpoena.

8. The production of Andrx documents from the HMR Litigation that are responsive to AHP's request would require the review of at least 60,000 pages of documents.

I declare under the penalty of perjury that the foregoing is true and correct.

Executed in New York, New York, on August 9, 2001

Colin A. Underwood

A

SUBPOENA DUCES TECUM

Issued Pursuant to Rule 3.34(b), 16 C.F.R. § 3.34(b)(1997)

1. TO

Andrx Corporation
c/o Colin A. Underwood, Esq.
Solomon, Zauderer, Ellenhorn, Frischer & Sharp
45 Rockefeller Plaza
New York, NY 10111

2. FROM

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

This subpoena requires you to produce and permit inspection and copying of designated books, documents (as defined in Rule 3.34(b)), or tangible things - or to permit inspection of premises - at the date and time specified in Item 5, at the request of Counsel listed in Item 9, in the proceeding described in Item 6.

3. PLACE OF PRODUCTION OR INSPECTION

Arnold & Porter
555 Twelfth Street, NW
Washington, D.C. 20004

4. MATERIAL WILL BE PRODUCED TO

Cathy A. Hoffman, Esq.

5. DATE AND TIME OF PRODUCTION OR INSPECTION

August 27, 2001 - 9:00 a.m.

6. SUBJECT OF PROCEEDING

In the matter of Schering-Plough Corporation, et al, Docket No. 9297

7. MATERIAL TO BE PRODUCED

See Attachment A

8. ADMINISTRATIVE LAW JUDGE

The Honorable D. Michael Chappell

Federal Trade Commission
Washington, D.C. 20580

9. COUNSEL REQUESTING SUBPOENA

Cathy A. Hoffman, Esq.

DATE ISSUED

JUL 19 2001

SECRETARY'S SIGNATURE

Donald S. Clark

GENERAL INSTRUCTIONS

APPEARANCE

The delivery of this subpoena to you by any method prescribed by the Commission's Rules of Practice is legal service and may subject you to a penalty imposed by law for failure to comply.

MOTION TO LIMIT OR QUASH

The Commission's Rules of Practice require that any motion to limit or quash this subpoena be filed within the earlier of 10 days after service or the time for compliance. The original and ten copies of the petition must be filed with the Secretary of the Federal Trade Commission, accompanied by an affidavit of service of the document upon counsel listed in Item 9, and upon all other parties prescribed by the Rules of Practice.

TRAVEL EXPENSES

The Commission's Rules of Practice require that fees and mileage be paid by the party that requested your appearance. You should present your claim to counsel listed in Item 9 for payment. If you are permanently or temporarily living somewhere other than the address on this subpoena and it would require excessive travel for you to appear, you must get prior approval from counsel listed in Item 9.

This subpoena does not require approval by OMB under the Paperwork Reduction Act of 1980.

ATTACHMENT A

SUBPOENA DUCES TECUM ISSUED TO: ANDRX CORPORATION

DOCUMENTS REQUESTED

1. All documents relating to any ANDA or NDA submitted by Andrx to the FDA for the manufacture and production of a 20 milliequivalent (mEq) potassium chloride product. This request includes, by way of example, but is not limited to:

   (a) All communications between the FDA and Andrx;
   (b) All communications between Schering and Andrx;
   (c) All communications between the FTC and Andrx;
   (d) All communications between Andrx and any third party;
   (e) All responsive internal communications.

2. All documents relating to the present or future, possible or actual, manufacture, production, and marketing of a 20 mEq potassium chloride product by any entity. This request includes, by way of example, but is not limited to:

   (a) All marketing and sales projections or forecasts and all communications relating to marketing and sales projections and forecasts;
   (b) All plans for the manufacture or marketing of the 20 mEq potassium chloride product and all communications relating to the likelihood of the manufacture or marketing of the product;
   (c) All communications relating to when the manufacture or marketing of the 20 mEq potassium chloride product is or was likely to occur;
   (d) All communications relating to Andrx's anticipated sales revenues, profits, royalties or other payments or income from or based on the marketing and sale of the 20 mEq potassium chloride product;
   (e) All documents related to Andrx's anticipated prices for its 20 mEq potassium chloride product or its policies and practices for determining the prices for its 20 mEq potassium chloride product;
   (f) All communications relating to Schering's present or future manufacture, sale and marketing of K-Dur 20, including but not limited to communications relating to the price and market share of K-Dur 20;
   (g) All communications relating to the possible manufacture, marketing, or sale of a 20 mEq potassium chloride product by any entity in addition to Schering, including but not limited to, Upsher-Smith, ESI, Elan, Teva, Andrx, or KV, including but not limited to communications relating to the anticipated prices and market shares of these products.

3. All documents relating to the present and future market for 20 mEq potassium chloride products. This request includes, by way of example, but is not limited to:

(a) All communications relating to which entities Andrx anticipated would manufacture and market 20 mEq potassium chloride products in the future and when these entities were likely to market their 20 mEq products;
(b) All forecasts and communications relating to the market shares of Schering, Andrx, and Andrx's potential competitors in the sale and marketing of 20 mEq potassium chloride products;
(c) All forecasts and communications relating to the price of any 20 mEq potassium chloride product that Andrx anticipated would be in the market at any time;
(d) All documents relating to competition between 20 mEq potassium chloride products and any other products.

4. All documents relating to any litigation, contemplated or actual, in any federal or state court, involving an ANDA or NDA submitted to the FDA for the manufacture and production of a 20 mEq potassium chloride product. This request includes, by way of example, but is not limited to:

(a) All communications between Schering and Andrx;
(b) All communications between Andrx and any third party;
(c) All communications between Schering and a third party or between two third parties;
(d) All pleadings, court documents, or court submissions;
(e) All proposed, tentative, or final settlement agreements.

5. All documents submitted to the FTC in response to or in connection with the "FTC generic drug study."

6. All documents that relate to any communications between Andrx and the FTC related to any potassium chloride product, of any level of dosage.

INSTRUCTIONS

1. This subpoena extends to all documents in Andrx's possession, custody, or control, wherever the documents may be located.

2. Except where otherwise specified, the requests contained in this subpoena are limited to documents created, generated and/or transmitted between January 1, 1995 and the present.

3. The requests contained in this subpoena do not require Andrx to produce those documents that were labeled with the Bates numbers Andrx SP 000001 to Andrx SP 005592 and previously submitted to the FTC. All copies of such documents bearing Bates numbers Andrx SP 000001 to Andrx SP 005592 that are different in any way from the originals submitted to the FTC must be produced pursuant to this subpoena.

4. The source and location of each responsive document shall be designated, including the person from whom it was obtained. The documents shall be produced either as they are

kept in the ordinary course of business or they shall be organized and labeled to correspond with the categories of the requests contained in this subpoena.

5. All documents shall be produced with all associated file labels, file headings, and file folders together with the responsive documents from each file, and each file shall be identified as to its owner or custodian; for any document originally stored in electronic media, the file name, path and directory information for each such document shall also be provided.

6. Except for privileged material, produce each responsive document in its entirety by including all attachments and all pages, regardless of whether they directly relate to the specified subject matter. Submit any appendix, table, or other attachment by either physically attaching it to the responsive document or clearly marking it to indicate the responsive document to which it corresponds. Except for privileged material, do not mask, cut, expunge, edit, or delete any responsive document or portion thereof in any manner.

7. If produced in hard copy, all pages now stapled or fastened together shall be produced stapled or fastened together, and shall include all attachments currently or previously appended to each document, regardless of whether such attachments themselves are responsive to this subpoena.

8. If produced electronically, the electronic file pertaining to each document shall be constructed to reflect all pages now stapled or fastened together and all attachments currently or previously appended to the hard-copy original from which the electronic image was generated, regardless of whether such attachments themselves are responsive to these requests.

9. All documents that cannot be legibly copied shall be produced in original form. All documents that are produced shall be originals or shall be like-colored photocopies of the originals.

10. Each page of each document produced shall bear a unique identifier that includes a symbol or abbreviation that identifies the producing party.

11. In addition to hard-copy documents, the search will include Andrx's electronically stored data. Sources of electronically stored data may include, but are not limited to:

(a) Personal computers ("PCs") and workstations; PCs, workstations, minicomputers and mainframes used as file servers, applications servers, or mail servers; laptops, notebooks, hand-held devices and other portable computers available for shared use; and home computers used for work related purposes;

(b) Backup disks and tapes, archive disks and tapes, and other forms of offline storage;

(c) Computers and related offline storage used by agents, consultants, and other persons as defined herein, which may include persons who are not employees of Andrx.

12. Each of these requests shall be construed independently and shall not be limited by any other request.

13. If, in answering the requests contained in this subpoena, you claim that any request, or a definition or instruction applicable thereto, is ambiguous, do not use such a claim as a basis for refusing to respond, but rather set forth as a part of the response the language you claim is ambiguous and the interpretation you have used to respond to the request.

14. In the event that more than one copy of a document exists, produce every copy on which there appears any notation or marking of any sort not appearing on any other copy (including routing or filing instructions) or any copy containing different attachments from any other copy.

15. If you refuse to disclose any document requested herein (or any portion thereof) on the grounds of privilege, identify in a privilege log each such document or portion thereof as to which the objection is made and, pursuant to FTC Rule of Practice 3.38A, with respect to each document so identified, state:

(a) the medium (e.g., electronic or paper), type (e.g., memorandum, letter, report, etc.), title, and length of the document;
(b) the existence and identity of any attachments to the document;
(c) the author(s) and addressee(s);
(d) the person(s) to whom any copy was furnished;
(e) the date of the document;
(f) the specific subject matter of the document;
(g) the document request herein to which the document responds; and
(h) the exact basis, legal or otherwise, for your claim that such document (or any portion thereof) need not be disclosed.

If an attachment to a document is also being withheld on the grounds of privilege, in addition to being identified as required by subpart (b), above, such attachment shall be identified in the privilege log as a separate document.

16. This subpoena is continuing in nature. If, after producing the requested documents, you obtain or become aware of any further documents responsive to this set of requests, you are required to produce such additional documents.

17. The documents requested shall be produced to the undersigned counsel for AHP at 555 Twelfth Street, NW, Washington, D.C., 20004, beginning on 15 days from the date this subpoena is served, with the production of all responsive documents to be completed within 15 calendar days thereafter. Pursuant to FTC Rule of Practice 3.38A, any claims of privilege shall be asserted no later than the date set for the production of the documents.

DEFINITIONS

1. The term "and" as well as "or" shall be read in the disjunctive, conjunctive, or both, as the case may be, consistent with an interpretation that results in the more extensive answer. The singular form of a word shall be interpreted in the plural and vice versa whenever appropriate to bring within the scope of this subpoena any information that might otherwise be construed to be outside their scope.

2. "FDA" means the United States Food and Drug Administration, and its divisions, agents, employees, attorneys, consultants, scientists, technicians, examiners, laboratories, representatives, officers, and all other persons acting on its behalf.

3. "FTC" means the United States Federal Trade Commission, including its employees, agents, attorneys, consultants, representatives, officers, and all other persons acting on its behalf.

4. "NDA" means a New Drug Application submitted to the FDA for approval for the manufacture and marketing of a pharmaceutical product.

5. "ANDA" means an Abbreviated New Drug Application submitted to the FDA for approval for the manufacture and marketing of a pharmaceutical product that is "bioequivalent" to an FDA approved, brand name pharmaceutical product.

6. "Schering" means respondent Schering-Plough Corporation, its predecessors, successors, assigns and present and/or former affiliates, corporate parents, divisions, or subsidiaries and any of its respective officers, directors, employees, partners, agents, attorneys, or any person acting on its behalf.

7. "K-Dur 20" means the 20 milliequivalent (mEq) potassium chloride supplement sold under that brand name by Schering.

8. "20 mEq potassium chloride product" means a potassium chloride sustained release product with a 20 milliequivalent dosage. "20 mEq potassium chloride product" means any form of potassium chloride sustained release product, e.g., tablets, capsules, powders, etc., and includes but is not limited to any product that is purportedly bioequivalent to Schering's K-Dur 20 potassium chloride product.

9. "Andrx" means Andrx Corporation, its predecessors, successors, assigns and present and/or former affiliates, corporate parents, divisions, or subsidiaries and any of its present or former officers, directors, employees, partners, agents, attorneys, or any person acting on its behalf.

10. "Elan" means Elan Pharmaceuticals Research Corporation, its predecessors, successors, assigns and present and/or former affiliates, corporate parents, divisions, or subsidiaries and any of its present or former officers, directors, employees, partners, agents, attorneys, or any person acting on its behalf.

11. "KV" means KV Pharmaceuticals Company, its predecessors, successors, assigns and present and/or former affiliates, corporate parents, divisions, or subsidiaries and any of its present or former officers, directors, employees, partners, agents, attorneys, or any person acting on its behalf.

12. "Teva" means Teva Pharmaceuticals, USA, Inc., its predecessors, successors, assigns and present and/or former affiliates, corporate parents, divisions, or subsidiaries and any of its present or former officers, directors, employees, partners, agents, attorneys, or any person acting on its behalf.

13. "ESI" means ESI Lederle, its predecessors, successors, assigns and present and/or former affiliates, corporate parents, divisions, or subsidiaries and any of its present or former officers, directors, employees, partners, agents, attorneys, or any person acting on its behalf.

14. "Upsher-Smith" means respondent Upsher-Smith Laboratories, Inc., its predecessors, successors, assigns and present and/or former affiliates, corporate parents, divisions, or subsidiaries and any of its present or former officers, directors, employees, partners, agents, attorneys, or any person acting on its behalf.

15. The term "FTC generic drug study" means the FTC requests for information and documents issued to brand name and generic manufacturers in 2001 pursuant to a study announced by the FTC in the Federal Register on October 17, 2000 at 65 Fed. Reg. 61334.

16. The term "person" means any natural person, firm, partnership, corporation, incorporated association, organization, joint venture, cooperative, governmental body or other form of legal entity.

17. The term "communication(s)" means any written or verbal contact, formal or informal, at any time or place, under any circumstance whatsoever, whereby information of any nature was transmitted or transferred, and includes, but is not limited to, conversations, discussions, telephone conversations, letters, notes, memoranda, reports and legal filings.

18. The terms "document" or "documents" include these terms as defined in 16 C.F.R. § 3.34(b) and, in addition, the original or drafts or any kind of written, printed, recorded or graphic matter or sound reproduction, however produced or reproduced, whether sent or received or neither, and all copies thereof which are different in any way from the original (whether by notation, indication of copies sent or received or otherwise) regardless of whether designated "Confidential," "Privileged" or otherwise and including, but not limited to, any correspondence, paper, book, account, drawing, agreement, contract, e-mail, handwritten notes, invoice, memorandum, telegram, object, opinion, purchase order, report, records, transcript, summary, study, survey, recording of any telephone or other conversation, interviews or notes of any conference. The terms "document" or "documents" shall also include data stored, maintained or organized electronically or magnetically or through computer equipment, translated, if necessary, by you into reasonably usable form, and film impression, magnetic tape and sound or mechanical productions of any kind or nature whatsoever.

19. The term "relating to" means, in whole or in part, addressing, analyzing, concerning, constituting, containing, commenting on, dealing with, describing, discussing, explaining, embodying, evidencing, identifying, referring to, reflecting, reporting on, setting forth, showing, summarizing, supporting, or stating.

20. The terms "each," "any," and "all" mean "each and every."

CERTIFICATE OF SERVICE

I, Robert L. Jones, hereby certify that on July 26, 2001, I caused a *Subpoena Duces Tecum* issued to Andrx Corporation to be served upon the following by Federal Express and facsimile:

Colin A. Underwood, Esq.
Solomon, Zauderer, Ellenhorn, Frischer & Sharp
45 Rockefeller Plaza
New York, NY 10111

On July 26, 2001, I caused a true and correct copy of the *Subpoena Duces Tecum* issued by American Home Products Corp. upon Andrx Corporation to be served upon the following persons by hand delivery or Federal Express:

Karen G. Bokat, Esq.
Federal Trade Commission
Bureau of Competition
601 Pennsylvania Ave., N.W.
Room S-3115
Washington, D.C. 20580

Laura S. Shores, Esq.
Howrey Simon Arnold & White LLP
1299 Pennsylvania Ave., N.W.
Washington, D.C. 20004

Christopher M. Curran, Esq.
White & Case LLP
601 13th Street, N.W.
Washington, D.C. 20005

Robert L. Jones
Arnold and Porter